DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2005

Abbott Vascular Devices
c/o Mr. Ric Ruedy
Director, Regulatory Affairs
400 Saginaw Drive
Redwood City, CA 94063

Re: K052454
Emboshield® Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: March 23, 2005
Received: September 6, 2005

Dear Mr. Ruedy:

This letter corrects our substantially equivalent letter of September 14, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Diana R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052454

Device Name: The Emboshield® Embolic Protection System

Indications For Use: The Emboshield Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.8 mm and 6.2 mm.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052454

APPENDIX A. 510(k) SUMMARY

Sponsor/Submitter:	Abbott Vascular Devices (on behalf of MedNova, Ltd) 400 Saginaw Drive Redwood City, CA 94063
Contact Person:	Debbie Cogan Regulatory Affairs Manager Phone:(650) 474-3263 Fax:(650) 474-3041
Date of Submission:	March 22, 2005
Device Trade Name:	Emboshield® Embolic Protection System
Device Common Name:	Embolic Protection System
Device Classification:	Class II
Regulation Number:	21 CFR 870.1250
Classification Name:	Device, coronary saphenous vein bypass graft, temporary, for embolization protection
Product Code:	NFA
Predicate Device:	Guidant RX Accunet Embolic Protection System (K042908)
Intended Use:	The Emboshield® Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.8 and 6.2 mm.
Device Description:	The Emboshield® Embolic Protection System is a temporary percutaneous transluminal filtration system designed to capture embolic material released during angioplasty and stent procedures within carotid arteries. The system consists of the following components: **RX BareWire™** The RX BareWire™ is a 0.014" PTFE coated stainless steel guidewire with a 3.0cm (0.014") platinum radiopaque distal tip section. The RX BareWire™ is available in two lengths, 315cm and 190cm and a variety of stiffness.

RX Delivery Catheter

The RX Delivery Catheter usable length is 135 cm. The crossing profile is between 0.048" and 0.051", depending on Filtration Element size. A pull handle is used to deploy the loaded Filtration Element from the pod. Two pairs of indicator bands are provided along the catheter shaft. A proximal pair (90 cm and 100 cm from the catheter tip) to indicate the catheter tip position during advancement through the guide catheter, and a distal pair to indicate the proximity of the RX exit port during catheter retraction. A radiopaque marker band is positioned proximal to the pod.

Filtration Element

The Filtration Element consists of a polyurethane membrane with internal Nitinol arms. There are two proximal triangular entry ports and multiple distal perfusion pores of 140microns. There is a proximal and a distal marker band. The Filtration Element is available in 3.0 mm, 4.0 mm, 5.0 mm and 6.0 mm diameters.

RX Retrieval Catheter

The RX Retrieval Catheter has a 139 cm usable length, a retractable Centering Catheter, and a distal expansile tip. The maximum outer diameter is 0.072''. A handle with a flushing port is situated at the proximal end. Two pairs of indicator bands are provided along the catheter shaft. Another proximal pair of indicator bands (90 cm and 100 cm from the catheter tip) allows indication of the catheter tip position during advancement through the guide catheter and a distal pair to indicate the proximity of the RX Retrieval Catheter exit port during catheter retraction. A radiopaque marker band is positioned approximately 3.5cm from the distal tip on the outer sheath.

Summary of Substantial Equivalence:

Abbott Vascular Devices has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that Emboshield Embolic Protection System is substantially equivalent to the currently marketed predicate device.

The Emboshield Embolic Protection System has the same intended use as the predicate device. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. *In vitro* and *in vivo* testing was conducted. The SECuRITY Registry Trial was conducted

enrolling a total of three hundred ninety nine (399) patients at 30 sites.

In summary, the results of the testing and clinical study support the safety and performance of the Emboshield device and its components for the intended indication when used in accordance with the Instructions for Use.